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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,061	02/25/1998	MATTHEW TODD GILLISPIE	GILLISPIE-1	6893

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/030,061

Applicant(s)

GILLSPIE ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 29-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 29-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

The request filed on 15 January 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/030,061 is acceptable and a CPA has been established. An action on the CPA follows.

Applicant's preliminary amendment in paper No. 20, filed on 15 January 2003 is acknowledged and entered. Following the amendment, claim 29 is amended, and the new claims 33-36 are added.

Currently, claims 29-36 are pending and under consideration.

Withdrawal of Objections and Rejections:

The objection of claim 29 is withdrawn in view of applicant's amendment.

The nonstatutory double patenting rejection, and the provisional obviousness-type double patenting rejection of claims 29-32 are withdrawn in view of the terminal disclaimer in paper No. 21 filed on 15 January 2003, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,207,641, and U.S. Patent No. 6,476,197, and in view of applicants argument. The terminal disclaimer has been recorded.

The rejection of claims 29-32 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's argument.

Formal Matters:

Claims 34 and 35 are objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. All limitations in claims 34 and 35 are present in the independent claim 29, as such, claims 34 and 35 are not further limiting claim 29.

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Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite for "a functional equivalent". "Said functional equivalent" is suggested as the claim is dependent from claim 29, which recites "a functional equivalent". Claim 34 is similarly indefinite.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-32 remain rejected, and claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ushio et al., EP 0 712 931 A2, or Okamura et al., US 5,912,324 and further in view of Mark et al., US 4,588,585, for the reasons of record set forth in the previous Office Actions, paper No. 15, at pages 5-6, and paper No. 17.

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Applicants argument in paper No. 20 has been fully considered, but is not deemed persuasive for reasons below.

With respect to claims 29-32, the applicant argues, at pages 7-8 of the response, that based on the teachings of Mark (cysteine residues of IL-1 and IFN- β , not involved in disulfide linkage), and the teachings of Ushio or Okamura (the number and position of Cys residues in IL-18), it would have been difficult even for a skilled person to predict whether one or more cysteine residues in IL-18 are replaceable while maintaining its biological activity, and that it is only the applicants who have found for the first time that IL-18 contains no disulfide linkage. This argument is not persuasive because, as addressed in the last Office Action, it is well known in the art that cysteine residues in many protein molecules can be substituted or deleted without affecting biological activities of the proteins, and to avoid undesirable intermolecular or intramolecular structures, and there is ample evidence in supporting such, which were exemplified in the previous Office Action. Although there is no exact prior art on the substitution or deletion of cysteine residues of IL-18, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make such modification based on the sequence taught by Ushio and Okamura. The person of ordinary skill in the art would have been motivated to do so for the advantage well known in the art, and making and testing such muteins based on the known sequence is well within the skilled artisan's purview. As the present invention merely claims the IL-18 having any one or more Cys residues replaced without specified position, it is rendered obvious by the prior art.

Additionally, as addressed in the last Office Action, the instant invention is similar to the situation in *Ex parte Mark*, which indicates that it is a routine in the art to make functional variants with deletion or replacement of cysteine residues for a given protein with known function.

The new claims 34-36 are rejected for the same reasons above.

With respect to claim 33, it is directed to a composition comprising an IL-18 and a functional equivalent thereof, and none of the prior art references teaches such a mixture. However, it would have been prima facie obvious to one of ordinary skill in the art to combine

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the two as they are functional equivalents. The instant situation is amenable to the type of analysis set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant method claims, given the teaching of the prior art of IL-18 and its variants maintaining the same functional activity, it would have been obvious to combine the two for the treatment because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful for the same purpose of treating diabetes. Thus, claims that require no more than mixing together of two known active ingredients with the same biological activity set forth *prima facie* obvious subject matter.

Conclusion:

No claim is allowed.

A handwritten signature in cursive script, reading "Lorraine Spector". The signature is written in dark ink and is positioned above the typed name and title.

LORRAINE SPECTOR
PRIMARY EXAMINER

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/26/03